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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,992	04/18/2001	Hui Tian	18781-006020	8880

20350 7590 06/16/2004

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,992

Applicant(s)

TIAN ET AL.

Examiner

Christian L Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11,13-15,17-74,76 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 19-30 and 33-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11,13-15,17,18,31,32,76 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on November 19, 2003, has been entered.
2. Claims 1-11, 13-15, 17, 18, 31, 32, 76, and 77 are under consideration in this Office Action.
3. The rejection of claims 1-11, 13-15, 17, 18, 31, 32, 76, and 77 under 35 U.S.C. 101 has been withdrawn since Applicants' arguments filed 05/21/2004 are deemed persuasive to overcome the utility rejection.

Claim Objections

4. Claim 2 is objected to because of the following informalities: Claim 2 is objected to because they recite non-elected subject matter, specifically, SEQ ID NOS: 5 and 6. Applicant is required to cancel the claims or amend the claims to recite the elected subject matter of SEQ ID NO: 3 and SEQ ID NO: 4.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 1-8, 10, 13-15, 17, 18, 31, 32, 76, and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or an isolated polynucleotide comprising SEQ ID NO: 4; does not reasonably provide enablement for any other

Art Unit: 1652

embodiment.

Applicants' arguments filed 05/21/2004 have been fully considered but they are not persuasive. Applicants' position is that the specification demonstrates how to make the claimed invention since the human SSG nucleotide sequence SEQ ID NO: 3 and the mouse SSG nucleotide sequence SEQ ID NO: 1 encode polypeptides that share 78% identity between their respective amino acid sequences shown in Exhibit B. Applicants argue that the specification teaches hybridization and amplification techniques that can be used to identify the claimed invention in DNA libraries or expression libraries. The Examiner disagrees for reasons of record and reasons stated below.

Teachings regarding screening and searching for the claimed invention using hybridization or PCR techniques is not guidance for making the claimed invention. Sequence identity is not a disclosure of how to make the claimed invention since sequence identity only indicates what percentage of nucleotides or amino acid residues are identical to a reference nucleotide or amino acid sequence. Sequence identity of SEQ ID NO: 4 to the *Drosophila brown* gene is not a disclosure that the claimed invention automatically has the properties or characteristics of the *Drosophila brown* gene. Furthermore, sequence identity is not teaching regarding the specific nucleotides to change in any polynucleotide to make the claimed polypeptide.

The specification provides guidance and examples for making an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or an isolated polynucleotide comprising SEQ ID NO: 4. However, the specification does not teach the specific amino acids and codons that can be altered to make the claimed polynucleotide that encodes a polypeptide that has 75%, 80%, 90%, or 95% identical to SEQ ID NO: 3 and still retains ABC sterol transporter activity. The specification does not teach the specific nucleotides that can be altered to make the claimed polynucleotide that has 80% identity to SEQ ID NO: 4.

The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that:

“...we do not have a common understanding of what constitutes a gene; we cannot invariably say that a particular sequence or fold has arisen via divergence or convergence; we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation” (see Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotide is enormous and entails selecting specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make a

Art Unit: 1652

polynucleotide that encodes a polypeptide that comprises an amino acid sequence that is at least 75%, 80%, 90%, or 95% identical to SEQ ID NO: 3 and determining by assays whether the polypeptide has ABC sterol transporter activity. Furthermore, such undue experimentation entails screening and searching for any polynucleotide that hybridizes to SEQ ID NO:4 under the moderately stringent hybridization conditions recited in claim 8, expressing the polynucleotide to make a polypeptide, and then determining by assays whether the polypeptide has ABC sterol transporter activity

Thus, such enormous experimentation is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no information is provided by the specification regarding the specific amino acid residues of the encoded ABC sterol transporter which cannot be changed in order preserve activity.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific amino acid residues which must be preserved to maintain ABC sterol transporter activity. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 2-8, 10, 13-15, 17, 18, 31, 32, 76, 77 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

7. Claims 1-11, 13-15, 17, 18, 31, 32, 76, and 77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 05/21/2004 have been fully considered but they are not persuasive. Applicants' position is that the amendment to the claims overcomes the rejection since the amendments define a particular structure and function. The Examiner disagrees for reasons of record and reasons stated below.

The claims are genus claims which are directed to any isolated nucleic acid encoding any SSG polypeptide comprising any amino acid sequence that is at least 75%, 80%, 90%, or 95% identical to SEQ ID NO: 3, any isolated nucleic acid comprising a nucleotide sequence at least about 80% identical to SEQ ID NO: 4, or any nucleic acid which hybridizes under moderately stringent or stringent hybridization conditions to SEQ ID NO: 4.

The specification defines "SSG polypeptide" as a transporter with the amino acid sequence of SEQ ID NO: 3, or any derivative, homolog, or fragment thereof. The specification does not provide a written description of the specific function and structure of any derivative, homolog, or fragment thereof as encompassed by the term "SSG polypeptide".

The recitation that the polypeptide comprises an ATP-binding cassette (ABC) family sterol transporter does not limit the claimed genus to a genus encompassing only nucleic acids

Art Unit: 1652

encoding ABC family sterol transporters since the recitation of "SSG polypeptide" encompasses any derivative, homolog, or fragment of a transporter polypeptide with the amino acid sequence of SEQ ID NO: 3

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 2-11, 13-15, 17, 18, 31, 32, 76, and 77 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

Amending the claims to recite that the phrase, "an isolated nucleic acid encoding an ATP-binding cassette (ABC) family sterol transporter", may overcome the rejection.


Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


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